

c.) Remarks

Claim 6, 16, 24, 30, 31, 37, 43, 49 and 50 have been amended in order to recite the present invention with the specificity required by statute. The subject matter of the amendment may be found in the specification as filed, e.g., at page 26, lines 1-2. Accordingly, no new matter has been added.

The Examiner required that Applicants affirm their provisional election to prosecute the invention of Group I, e.g., claims 1-38 and 43-51. By the above cancellation of nonelected claims 39-42, that provisional election is hereby affirmed.

Claim 51 is objected to because the word "food" in line 1 is misspelled. This objection is mooted by the above cancellation of this claim.

Claims 1-5, 7-15, 17-23, 25-30, 32-37, 43-49 and 51 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In response, this rejection is overcome by amending claims 30, 37, 43 and 49 to recite "isolated" in conformity with the Examiner's kind suggestion.

Claims 1-3, 8-13, 45-47 and 51 under 35 U.S.C. §102(b) as being anticipated by Yokogawa et al (JP 410046142A), claims 1-4, 7-14, 45-48 and 51 as anticipated by Yamashita (JP 405056772A), claims 1, 2, 4, 5 and 8 as anticipated by Yamahara et al. (XP002220391), and claims 1, 2, 4, 5 and 8 as anticipated by Nakamoto et al. (J. Prosthet. Dent.) These rejections are mooted by the above cancellation of the rejected claims without prejudice or disclaimer.

Claims 1-3, 7-13, 17-21, 25-28, 32-35, 45-47 and 51 are rejected under 35 U.S.C. §102(e) as being anticipated by Konishi (U.S. Patent No. 6,541,041) and claims 1, 4, 7-11, 14, 17-19, 22, 25, 26, 29, 32, 33, 36, 45, 48 and 51 are rejected as anticipated by

Levinson et al. (U.S. Patent No. 6,479,545)<sup>1</sup>. These rejections too are mooted by the previous cancellation of the rejected claims without prejudice or disclaimer.

Claims 15, 23, 30, 37, 43, 44 and 49 are rejected under 35 U.S.C. §103(a) as being obvious over Yamahara et al. (XP002220391)<sup>2</sup> in view of Levinson et al. (U.S. Patent No. 6,479,545). Finally, claims 6, 16, 24, 31, 38, 43 and 50 as obvious over Fuji Rebio (XP002220392) in view of Konshi (U.S. Patent No. 6,541,041) and claim 44 is rejected as obvious over this art in further view of Fukunaga (U.S. Patent No. 5,525,340).

As before, the rejection of claims 15 and 23, at least, is mooted in view of their cancellation. As to the remaining claims, the rejections are respectfully traversed. However, prior to setting forth their bases for traversal, Applicants would like to briefly point out the salient features of the present invention and *inter alia*, its patentable nature over the prior art.

The present invention generally relates to an agent ("extract") obtained by extracting with alcoholic media a residue obtained by extracting a plant of the family *Saxifragaceae* with aqueous media (claims 6, 16, 24, 31, 38 and 50). The present invention also relates to isolated *Hydrangea* species (claims 30, 37 and 49) and to a method utilizing isolated *Saxifragaceae* (claim 43).

As discussed below, these features are neither taught nor suggested by the prior art. For completeness of the record, the Examiner's remaining rejections are addressed in turn.

Yamahara teaches a methanol extract of *Hydrangea macrophylla* Seringe

<sup>1</sup>/ The filing dates of Konishi and Levinson are respectively January 27, 2000 and September 30, 1999, which are before Applicant's priority date.

<sup>2</sup>/ Journal of the Pharmaceutical Society of Japan, Vol. 114, No. 6 (1994), pages 401-413.

var. *Thunbergii* Makino. In response, only claims 30, 37 and 49 relate to *Hydrangea*. As to these, Yamahara does not teach the species of claims 30 or 49, or the process of claim 37.

Nor is this deficiency overcome by the secondary reference to Levinson, which teaches at best that herbs (among them *hydrangea*, see column 14, line 37) may be administered in various forms. However, Levinson does not teach or suggest Applicants' noted species or therapeutic method.

Fuji Rebio simply teaches that tannins from *Saxifraga stolonifera* can be utilized in treatment of hepatitis B. However, Fuji Rebio does not teach or suggest any method for obtaining the tannins as recited in claims 6, 16, 24, 31, 38 or 50, or the therapeutic method of claim 43. Again, these deficiencies are not met by Konishi.

Konishi teaches extracting soluble silicon compounds from *Saxifraga stolonifera* (see column 5, line 8). The Examiner acknowledges Konishi utilizes a mixture of water and ethanol and does not teach or suggest Applicants' two step extraction. However, the Examiner contends

Applicant has not established the criticality of the two-step extraction process as compared to the one-step extraction process disclosed by the prior art, and there is no comparable example in the specification to demonstrate that the claimed extraction process provides some unusual and/or unexpected results.

In response, Applicants respectfully wish to invite the Examiner's attention to review Examples 8 and 10 found at specification pages 31 and 32. Example 8 uses 3 wt % of the powder produced in Example 2 (page 29) and Example 10 uses 1 wt % of the powder produced in Example 5 (pages 29-30). In Example 2, 1 kg *Hydrangea Dulcis Folium* is extracted twice with 10 l of a 60% aqueous solution of ethanol; in Example 5, 1 kg *Hydrangea Dulcis Folium* is extracted with 20 l water and the extract residue is

extracted with 20 ℥ 60% ethanol.

Since Example 2 is representative of Konishi, Example 8 is representative of the Examiner's combination of Fuji Rebio taken with Konishi. Example 10 is representative of the claimed invention.

As seen in Table 1 of Example 16 (see specification page 36), the feed of Example 10 is twice as effective with respect to ameliorating rat liver hepatopathy compared to the feed of Example 8. Moreover, since Example 8 includes three weight % of powder as compared to one weight % in Example 10, the present invention is actually six times more effective than the Examiner's proposed combination of prior art.

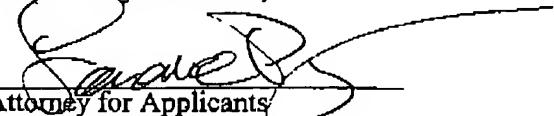
Respectfully submitted, this showing is both unusual and unexpected.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 6, 16, 24, 30, 31, 37, 38, 43, 44, 49 and 50 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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